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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/981,020 | 10/16/2001 | Daniel S. Kohane | 0492611-0417 (MIT 8966) | 5504 |

24280 7590 05/21/2003

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| EXAMINER | |
|---|---|
| DI NOLA BARON, LILIANA | |
| **ART UNIT** | **PAPER NUMBER** |
| 1615 | 12 |

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/981,020 | KOHANE ET AL. | |
| | Examiner | Art Unit | |
| | Liliana Di Nola-Baron | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) *21,22,26,29,31-36,38-45 and 66-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,23-25,27,28,30,37 and 46-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I, claims 1-65, in Paper No. 9 is acknowledged. Within Group I, Applicant has elected without traverse the following species: dipalmitoylphosphatidylcholine (claim 25) as the lipid, albumin (claim 30) as the protein and lactose (claim 37) as the sugar. Dipalmitoylphosphatidylcholine is a naturally occurring phosphatidylcholine, and it acts as an emulsifier and surfactant. Accordingly, claims 1-20, 23-25, 27, 28, 30, 37 and 46-65 will be examined in this Office action. Claims 21, 22, 26, 29, 31-36, 38-45 and 66-79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and to a nonelected species, there being no allowable generic or linking claim.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding claim 28, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Specifically, it is not clear whether the claimed fatty alcohols, surface active fatty acid and sorbitan fatty acid ester are limited to those following the phrase "such as", or the

compounds following the phrase "such as" are just a few examples of the compounds claimed in the invention.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-7, 13, 16, 18-20, 23-25, 27, 28, 30, 37, 46, 57-61, 63 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Moynihan (U.S. Patent 5,589,189).

Moynihan discloses a process for forming liposome-encapsulated hemoglobin and teaches that the compositions are formed by adding to a neutral lipid, such as dipalmitoylphosphatidylcholine (DPPC), hemoglobin dispersed in sucrose or lactose solution and human serum albumin, and filtering the resulting compositions to produce particles having a median size of 0.09-0.15 microns (See col. 5, lines 1-58). Liposomes, classified in class 424/ 450, are microparticles, thus, the patent teaches microparticle compositions comprising an active agent (hemoglobin) encapsulated in a matrix comprising a lipid (DPPC), a protein (human serum albumin) and a sugar (lactose), as claimed in claims 1 and 2 of the instant application, or the agent is encapsulated in a matrix comprising at least two of the above components, as claimed in claims 3-6 of the application.

With respect to the subject matter claimed in claims 7, 13 and 16 of the application, the process claimed in claim 1 of the patent comprises forming a liposome dispersion containing a therapeutic or an imaging (diagnostic) agent, and the hemoglobin disclosed by the patent (See col. 5, lines 26-28) is a protein, thus the patent meets the limitations of claims 7, 13 and 16.

The dipalmitoylphosphatidylcholine disclosed by the prior art, being a naturally occurring phosphatidylcholine with no charge, an emulsifier and a surfactant, meets the limitations of claims 18-20, 23-25, 27 and 28 of the instant application.

Moynihan provides particles comprising human serum albumin and lactose (See col. 5, lines 34-42), thus the patent meets the limitations of claims 30, 37 and 46 of the instant application.

With respect to the size of the microparticles claimed in claims 57-61 of the application, Moynihan teaches that the liposomes of the invention have a median size of 0.09 to 0.15 microns.

Regarding the method of administering the particles claimed in claims 63 and 64 of the application, Moynihan teaches that the liposome fluid of the invention can be administered to patients as a blood substitute by transfusion (See col. 1, lines 8-12) and the aqueous dispersions of liposomes can be delivered intravenously (See col. 2, line 67 to col. 3, line 2), thus the patent contemplates injection of the liposome composition into a patient.

The liposome compositions provided by Moynihan and their administration to a patient meet the limitations of claims 1-7, 13, 16, 18-20, 23-25, 27, 28, 30, 37, 46, 57-61, 63 and 64 of the instant application, as the patent contemplates compositions comprising an agent encapsulated in a matrix comprising lipid, protein and sugar, and a method of administering the microparticles to a patient. Thus, Moynihan anticipates the claimed invention.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 3, 4 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Bernstein et al. (U.S. Patent 6,423,345).

Bernstein et al. discloses polymer matrices in the form of microparticles, wherein a lipid, preferably dipalmitoylphosphatidylcholine (DPPC), is integrated into the polymeric matrix (See col. 1, lines 10-66 and col. 2, lines 15-48).

With respect to the matrix components, Bernstein et al. teaches that the matrix can be formed of synthetic or natural polymers, including proteins, such as albumin, and polysaccharides (sugars) (See col. 3, line 31 to col. 4, line 22), thus the patent contemplates a matrix made of a synthetic polymer and lipid, as claimed in claim 3, or lipid and protein, as claimed in claim 4, or lipid and sugar, as claimed in claim 5 of the instant application.

With regard to the limitation, that the agent is encapsulated in a matrix, Bernstein et al. includes therapeutic and prophylactic agents among the active agents, which can be incorporated into the matrix (See col. 6, line 56 to col. 7, line 5).

With respect to the pharmaceutical compositions of claims 3, 4 and 5, Bernstein et al. teaches that the microparticles of the invention can be administered as a powder, or formulated in tablets or capsules, or suspended in a solution with pharmaceutically acceptable carriers (See col. 9, lines 35-47).

The microparticle compositions disclosed by Bernstein et al. meet the limitations of claims 3, 4 and 5, as the patent contemplates pharmaceutical compositions comprising microparticles of an agent incapsulated in a matrix comprising the components claimed in the instant application. Thus, the patent anticipates the claimed invention.

8. Claims 1-7, 13, 18-20, 23-25, 27, 28, 30, 37, 46-59 and 62-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwards et al. (U.S. Patent 5,985,309).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor

of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Edwards et al. provides a method for preparing particles comprising insulin, albumin, lactose and dipalmitoylphosphatidylcholine (DPPC), or particles comprising albuterol, albumin, lactose and dipalmitoylphosphatidylcholine (DPPC), said method comprising spray drying a solution containing the active ingredient, the lipid, protein and sugar (See Examples 9 and 14). Thus, the particles disclosed by Edwards et al. comprise an agent encapsulated in a matrix comprising lipid, protein and sugar, as claimed in claims 1 and 2, or at least two of the above components, as claimed in claims 3-6, and provides a method for producing said particles as claimed in claim 62 of the instant application.

With respect to the limitations of claims 7 and 13, the insulin and albuterol encompassed by the prior art are therapeutic agents, and insulin is a protein.

The dipalmitoylphosphatidylcholine disclosed by the prior art, being a naturally occurring phosphatidylcholine with no charge, an emulsifier and a surfactant, meets the limitations of claims 18-20, 23-25, 27 and 28 of the instant application.

Edwards et al. provides particles comprising albumin and lactose (See Examples 9 and 14), thus the patent meets the limitations of claims 30, 37 and 46 of the instant application.

With respect to the ratio claimed in claim 47 and the amount ranges of the lipid, protein and sugar recited in claims 48-56, Example 14 teaches that the active agent is encapsulated in a matrix comprising 60% DPPC, 18% albumin, 18% lactose, thus the ratio of lipid to protein to sugar is 3:1:1, as claimed in the instant application, and the amount ranges disclosed by Edwards et al. for the lipid, protein and sugar meet the limitations of claims 48-56.

Edwards et al. teaches that the particles of the invention have a diameter between 5 and 30 microns, or even 2 microns (See Col. 9, lines 47-66)), thus the patent meet the limitations of claims 57-59 of the instant application.

Regarding the method of administering an agent claimed in claims 63 and 64 of the application, Edwards et al. teaches that the particles of the invention were administered to guinea pigs by inhalation or injection (See Examples 12 and 14).

The particles and methods of producing and administering said particles disclosed by Edwards et al. meet the limitations of claims 1-7, 13, 18-20, 23-25, 27, 28, 30, 37, 46-59 and 62-64 of the instant application, as the reference contemplates pharmaceutical compositions comprising microparticles of an encapsulated agent, a method of preparing said microparticles comprising contacting an active agent with a lipid, a protein and a sugar and spray drying the mixture obtained, and a method of administering said microparticles comprising injecting the microparticles into the patient. Thus, the patent anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 2, 6, 7, 12-20, 23-25, 27, 28, 30, 37, 46-60 and 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein et al. (U.S. Patent 6,423,345) in view of Stricker et al. (U.S. Patent 5,633,002).

Bernstein et al. discloses polymer matrices in the form of microparticles, wherein a lipid, preferably a phospholipid and specifically dipalmitoylphosphatidylcholine (DPPC), is integrated into the polymeric matrix (See col. 1, lines 10-66, col. 2, lines 15-48 and col. 5, lines 1-65), and teaches that the matrix can be formed of synthetic or natural polymers, including proteins, such as albumin (See col. 3, line 31 to col. 4, line 22). Dipalmitoylphosphatidylcholine is an emulsifier and a surfactant, thus the patent contemplates a matrix made of a lipid and protein, and specifically albumin and dipalmitoylphosphatidylcholine, which are matrix components claimed in claims 1, 2, 6, 18-20, 23-25, 27, 28 and 30 of the instant application.

With respect to the presence of the sugar in the matrix claimed in claims 1, 2, 6, 7, 12-20, 23-25, 27, 28, 30, 37, 46-60 and 62-65 of the instant application, Bernstein et al. provides the general teachings that the microparticles can be combined with bulking agents, including sugars, such as lactose (See col. 10, lines 6-10), but the patent does not specifically teach that the bulking agent is a matrix component. However, Bernstein et al. teaches that pore forming agents can be

included in an amount of 0.01-90% to increase matrix porosity and pore formation during the production of the matrices, and the pore forming agent can be added to the polymer solution during spray drying (See col. 9, lines 14-31). Sugars (See Stricker et al. below) are routinely used in the art as pore forming agents.

Bernstein et al. contemplates pharmaceutical compositions comprising the microparticles of the invention, as it teaches that the microparticles of the invention can be administered as a powder, or formulated in tablets or capsules, or suspended in a solution with pharmaceutically acceptable carriers (See col. 9, lines 35-47).

With regard to the agents claimed in claims 7 and 12-17 of the application, Bernstein et al. teaches that therapeutic and prophylactic agents can be incorporated into the matrix and includes proteins, sugars, steroids (lipids) and vasodilators among the drugs delivered by the invention (See col. 6, line 56 to col. 7, line 5). The agents described by Bernstein et al. as those that may be labeled with a fluorescent label or an enzymatic or chromatographically detectable agents (See col. 6, lines 61-63) are diagnostic agents.

With respect to the amounts of lipid and protein claimed in claims 48-53 of the instant application, Bernstein et al. teaches that the content of the lipid in the matrix is 0.01-60% in relation to the content of the polymer (See col. 6, lines 18-21) and the amount of polymer (protein) is 0.1-60% (See col. 4, lines 62-64). Thus, the patent contemplates an amount of lipid up to 36%.

With respect to the size of the microparticles claimed in claims 57-60 of the application, Bernstein et al. teaches that the microparticles of the invention are manufactured with a diameter suitable for the intended route of administration, and discloses particles for intravascular administration having a diameter of 0.5 to 8 microns (See col. 2, lines 20-27).

With respect to the method of preparing the microparticles claimed in claim 62, Bernstein et al. teaches that the microparticles of the invention can be produced by spray drying by dissolving the polymer (protein) and the lipid in the appropriate solvent, dispersing the active agent into the polymer solution, and then spray drying the polymer solution to form microparticles (See col. 8, lines 18-33). The patent teaches that a pore-forming agent can be added to the polymer solution during spray drying (See col. 9, lines 14-31).

With regard to the method of administering an agent claimed in claims 63-65 of the application, Bernstein et al. teaches that the microparticles are combined with a pharmaceutically acceptable carrier and administered to a patient by injection into a blood vessel, subcutaneously, intramuscularly or orally (See col. 9, line 64 to col. 10, line 6). Oral administration implies placing the microparticles in the oral cavity of the patient, thus the patent contemplates placing the microparticles in a body cavity of the patient, as claimed in claim 65 of the instant application.

With respect to the ratio of lipid to protein to sugar claimed in claim 47 of the application, the amount of lipid in relation to the amount of protein and pore forming agent disclosed by the prior

art is lower than the amount claimed in the instant application. Applicant has not established the criticality of the high ratio of lipid claimed in the instant application and there is no comparable example in the specification to demonstrate that the claimed high ratio of lipid provides some unusual and/or unexpected results. It appears to the examiner that the higher ratio of lipid does nothing additional to the compositions of the invention, especially in view of the teachings of the prior art, that the hydrophobic compound integrated in the polymeric matrix modifies the diffusion of water into the microparticle and the diffusion of solubilized drug out of the matrix (See col. 2, lines 8-11).

Thus, Bernstein et al. provides microparticles comprising an agent encapsulated in a matrix made of a lipid, protein and pore forming agent, method of preparing said microparticles and method of administering said microparticles to a patient. The patent is deficient in the sense that it does not specifically teach that sugars are pore-forming agents.

Stricker et al. provides an implantable biodegradable system comprising a polymer, plasticizers and a pore forming agent, specifically lactose, as claimed in claim 37 of the instant application, in an amount of up to 50%, for releasing an active substance (See col. 1, lines 41-56). Stricker et al. teaches that the pore forming agent controls the release of the active substance, and lactose is preferred among the monosaccharides and disaccharides used in the invention (See col. 3, lines 14-33). The amount of pore forming agent contemplated by Bernstein et al. and the amount of sugar contemplated by Stricker et al. are in the amount range claimed by Applicant in claims 54-56 of the instant application.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Bernstein et al. by including sugar in the matrix, and specifically lactose, as pore forming agent, as taught by Stricker et al., to devise microparticles for the controlled delivery of drugs. The expected result would have been a successful microparticle composition, and successful methods of preparing said composition and administering said composition to a patient. Because of the teachings of Bernstein et al., that pore forming agents can be included in the matrix of the microparticles to increase matrix porosity, and the teachings of Stricker et al., that the presence of lactose in the matrix controls the release of the active agent, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful in delivering an active agent to a patient. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

11. Claims 8-11 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein et al. in view of Stricker et al., as applied to claims 1, 2, 6, 7, 12-20, 23-25, 27, 28, 30, 37, 46-60 and 62-65 above, and further in view of Goldenheim et al. (U.S. Patent 6,534,081).

The teachings of Bernstein et al. and Stricker et al. have been summarized above. The prior art is deficient in the fact, that it does not specifically include the anesthetics recited in claims 8-10 of the application and anticonvulsant agents, as claimed in claim 11, among the therapeutic agents

encapsulated in the microparticles of the invention, and it does not teach microparticles having a diameter of less than 500 nanometers, as claimed in claim 61 of the instant application.

Goldenheim et al. provides sustained release dosage forms comprising a local anesthetic and an augmenting agent, and includes bupivacaine, dibucaine, tetracaine and lidocaine among the preferred local anesthetics used in the invention (See col. 3, line 50 to col. 4, line 51). Goldenheim et al. teaches that the local anesthetic is prepared in matrices of controlled release injectable microspheres (See col. 5, lines 60-64), and the formulations of the invention are suitable for administration in all body spaces and cavities (See col. 6, lines 55-59). Goldenheim et al. discloses formulations comprising microparticles comprising a local anesthetic, an augmenting agent and a sustained release polymer selected from synthetic polymers, proteins, polysaccharides and combinations thereof (See col. 7, lines 20-47). Thus, the patent provides the general teachings that local anesthetics can be delivered by microparticle compositions and specifically discloses the compounds recited in claims 8-10 of the instant application.

With respect to claim 11, Goldenheim et al. includes anticonvulsants among the augmenting agents incorporated in the compositions of the invention (See col. 12, lines 9-12).

With regard to the particle size claimed in claim 61, Goldenheim et al. defines microparticles as having a size range suitable for injection, infiltration or infusion into a desired site of administration (See col. 11, lines 8-16), and contemplates the use of liposomes as drug delivery

systems and teaches that the size of the liposomes may vary between 100 nm and 10 microns (See col. 21, lines 46-67).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Bernstein et al. and Stricker et al. with the teachings of Goldenheim et al., to obtain microparticles for the controlled delivery of local anesthetics and anticonvulsant drugs and modify the size of the microparticles according to the desired site of administration. The expected result would have been successful microparticle compositions for the delivery of local anesthetics and drugs. Because of the combined teachings of Bernstein et al. and Stricker et al., that microparticle formulations comprising an agent encapsulated in a matrix comprising lipid, protein and sugar are suitable for the administration of drugs, and the teachings of Goldenheim et al., that local anesthetics and anticonvulsants may be delivered using microparticle formulation, and the size of the particles may be varied according to the intended route of administration, one of ordinary skill in the art would have a reasonable expectation that the compositions claimed in the instant application would be successful in delivering an active agent to a patient. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

Liliana Di Nola Baron

May 19, 2003

Liliana Di Nola-Baron

Patent Examiner

Art Unit 1615